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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,797	09/13/2001	John Walker		9643

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

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03/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/857,797	**Applicant(s)** WALKER, JOHN	
	Examiner YUNSOO KIM	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *23-38*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Michael Szperka/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 23-38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,228,262A, of record, in view of WO99/27959, of record, and U.S. Pat. No. 4,900,549, of record, for the reasons set forth in the office action mailed 2/17/09.

The '262 application teaches a composition comprising a GnRH- diphtheria toxoid (DT) conjugate and an alum (aluminum hydroxide) as an adjuvant (claims 1-10). The '262 publication further teaches that GnRH is also known as LHRH (p. 1, line 21) and the composition comprising 20ug of GnRH-DT (p. 18).

The disclosure of the '262 publication differs from the instant claimed invention in that it does not teach the use of ionic polysaccharide (e.g. DEAE-dextran) and an immuno-stimulating complex comprising a saponin and a cholesterol as in claims 23-38.

The '959 publication teaches an adjuvant composition comprising a saponin and a DEAE-dextran (claims 1-22). The '959 publication teaches that the saponin is QuilA (Example 3), that said adjvuant composition improves adjuvanicity synergically (p. 2-3), induces long lasting antibody responses and is suitable for use with various antigens (p. 7-8).

Moreover, the '959 publication teaches that a common vaccine formulation comprises an antigen and aluminum hydroxide gel (alum) as an adjuvant and there are some problems associated with this adjuvant. The alum adjuvant often fails to induce sufficient immune response and it is not acceptable for routine use because of inflammation, granulomas, ulceration and other lesions at the injection sites (p. 1-2, overlapping paragraph). The referenced adjuvant composition comprises saponin and DEAE-dextran enhances the effectiveness of an antigenic substance (p. 2).

Given that the mass ratio between the DEAE-dextran and saponin of about 125 is recited in claim 29, claim 29 is included in this rejection because the '959 publication discloses the upper range of saponin is 1mg/ml and the upper range of the DEAE-dextran is 150mg/ml (claims 14 and 16) which results in about 150 mass ratio. In light of this, claims 30, 31 and 35 reciting particular concentration of 10-100mg of DEAE-dextran and 80-800ug of saponin as the referenced concentrations of the saponin and DEAE-dextran are encompassed (claims 14 and 16).

The '549 patent teaches the addition of a cholesterol in adjuvant compositions comprising Quil-A and that the cholesterol stabilizes antigenic species and improves immunogenic activity (col. 1, lines 45- 68, col. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ and/or substitute alum adjuvant as taught by the '262 publication with an adjuvant composition comprising DEAE-dextran, saponin and cholesterol as taught by the '959 publication and the '549 patent.

One of ordinary skill in the art would have been motivated to do so because the adjuvant composition taught by the '959 publication and the '549 patent improves overall immune response by providing an improved adjuvant activity. The Quil-A and DEAE-dextran adjuvant taught by the '959 publication enhances the effectiveness of an antigenic species in stimulating an immune responses to a much greater extent than alum adjuvant and the cholesterol stabilizes antigenic species and improves immunogenic activity.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references ad there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 3/3/10 have been fully considered but they were not persuasive.

Applicant has asserted that the prior office action did not specifically point out what was misleading from Applican't previous response and thus has requested a new due date.

Applicant has interpreted the teachings of the '959 publication is limited to 3 component composition which requires an immunoadjuvant oil . However, the component disclosed in the '959 publication recites "comprising" and this includes other unrecited components in addition to the recited components. Applicant is deemed to interprete what is disclosed in the '959 publication is not required in the claimed invention and has asserted that the combination of the references teaches away from the claimed invention.

However, the claimed composition recites "consiting essentially of" and this phrase does not exclude immunoadjuvant oil. In order to specifically exclude immunoadjuvant oil or other component s from the claimed invention and the phrase "consisting of" may be used in the claimed composition to limit to include onlyan isonic polysaccharide, saponin, and cholesterol. The claimed invention as is currently amended does not exclude addition of other components. Applicant has argued the limitations that are not claimed.

The currently amended limitation reciting "consisting essentially of " does not exclude other active components. The transitional phrase "consisting of " excludes any components not specified in the claim but "consisting essentially of" is construed as equivalent to "comprising". Moreover, the specification of the instant application does not define what is encompassed by active components. See MPEP 2111.03.

Further, Applicant's assertion that the combination of the references teaches away the use of cholesterol is misleading. Applicant has asserted that the '959 publication uses mineral oil as an essential adjuvant composition. Note that the '959 publication does not exclude cholesterol in the composition comprising a saponin. Rather, the '959 publication discloses the use of cholesterol with Quil A saponin (p.2, lines 14-16) and the '549 patent specifically teaches the use of cholesterol in the presence of Quil-A to stabilize antigenic species and improves immunogenic activities. Therefore, the combination of the references is obvious.

Yunsoo Kim
Patent Examiner
Technology Center 1600
March 11, 2010

/Michael Szperka/
Primary Examiner, Art Unit 1644